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Innovative COVID-19 Ventilator Design with Significant Improvement of Expiratory Positive Airway Pressure

[1]**Smallwood, Craig, [2]McBagonluri Fred (PhD), [3]Tetteh Douglas Ayitey & [4]Acakpovi Amevi**
[1]Boston Children Hospital, Boston, MA USA.
[2]Academic City University College, Haatso, Ghana
[3]University of Ghana, Accra, Ghana
[4]Accra Technical University, Accra, Ghana
E-mails: fred.mcbagonluri@acity.edu; douglas_ayitey@yahoo.com; acakpovia@gmail.com

ABSTRACT

This paper deals with the constructive design of an innovative and low-cost mechanical ventilator to aid respiration for acute COVID19 patients by improving the Expiratory Positive Airway Pressure (PEEP). The rise in mortality due to COVID19 pandemic is unprecedented and this is mainly due to severe deterioration of the respiratory system including inflammation of lung and respiratory tract leading to acute respiratory distress. Although ventilators are mostly used in the continuum of care as solution to this challenge, their design requires some specific considerations, sophisticated electronics and software systems that are often outside of the financial wherewithal of the world's most vulnerable. These ventilators are often high-end and technological advanced devices that although convenient, come at high cost and may be out of the financial reach of the world's most vulnerable to the prevailing COVID-19 pandemic. This paper provides the design for a simplified, relatively affordable, and specifically targeted devices to help deal with the COVID-19 effects on the respiratory tract. The design of a low-cost novel mechanical ventilator is considered in this paper. The components of the fabrication and design as well as the steps taken to actualize the artefact are discussed. The SMALLWOOD design does not require any electronic components and can be deployed in the most deprived areas in the world where access to electricity is nonexistent.

Keywords: COVID19, Ventilator, Respiratory Tract, Expiratory Positive Airway Pressure (PEEP)

1. INTRODUCTION

A ventilator is a bedside machine that aids patients, who are unable to breath on their own. Ventilators are used on patient undergoing general anesthetic procedure(s) or those suffering acute pulmonary distress. Breathing challenges can occur in patient because of post-surgery recovery, accidents or due to acute respiratory distress induced by Covid-19.

The human body needs a constant supply of oxygen. Oxygen is acquired through inhalation. Carbon dioxide produced by the body must be exhaled. The transition of oxygen to the body goes through a complex web of biological subsystems. Breathing starts when air is inhaled into the nose or mouth. The inhaled air travels down the back of the throat into the windpipe, which is divided into air passages called bronchial tubes. The bronchial tubes as they pass through the lungs split up into smaller air passages called bronchioles.

The bronchioles then end-up in tiny balloon-like air sacs called alveoli. The human body has about 600 million alveoli []. The alveoli are surrounded by a mesh of tiny blood vessels called capillaries. The capillaries are the transit channels for oxygen from inhaled air to pass into your blood stream. After absorbing oxygen, blood travels to the heart. The heart then pumps it throughout the body to the cells of tissues and organs to sustain life. This complex biological process in times of distress is supplanted or augmented by a ventilator. The ventilator ensures that the aveoli remain inflated and those that have collapsed or partially filled to be refilled. A typical ventilator has three key integrated subsystems: Patient Interface, Air Compression System, and Intelligent Controls Systems. Ventilators thus support oxygen delivery to the patient and the exit of CO2. The integration of complex electronics into ventilator system results in high cost of manufacture and end use organizations.

There are three methods by which oxygen is delivered to the patient: (i) Face mask connected to an oxygen tank (ii) Facemask connected to CPAP/BiPAP (iii) Endotracheal intubation (Intubation plus Mechanical ventilation). The first two methods are considered non-evasive and the third is considered evasive. Ventilators are used in surgery to: (1) Deliver anesthesia (2) Prevent aspiration syndrome (2) Control PaO2 and PaCo2). The Covid-19 disease, a rising international cause of morbidity and mortality, is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which mainly targets the respiratory tract, and causes widespread severe inflammation in the lung. According to Murthy, Gomersall & Fowler (2020), approximately 14% of all people with covid-19 develop Type 1 respiratory failure (T1RF), and a further 5% will become critically unwell. In addition to this, a high number of patients develop acute respiratory distress syndrome (ARDS) and would require respiratory support (Vardhana & Wolchok, 2020).

ARDS is a clinical phenomenon which is caused by a development of bilateral infiltrates and hypoxemia, defined as a decrease in the ratio of arterial PO_2 to inhaled FiO_2 (Thompson et al., 2017). Subsequently, almost all Covid-19 patients, who develop ARDS require mechanical ventilation (Bhatraju et al., 2020; Wu et al., 2020). Common methods of such ventilation are either invasive or non-invasive. Invasive ventilation is positive pressure delivered to the patient’s lungs via an endotracheal tube or a tracheostomy tube, whilst non-invasive ventilation (NIV), is a type of respiratory assistance, without an invasive airway, provided via a face mask to the patient’s upper airway (Margutti, Greco, Brambilla, Maraffi & Cosentini, 2017; Rajendram, Khan & Preedy, 2017). The application of NIV has increased greatly over the past two decades and has now become an integral tool in the management of both acute and chronic respiratory failures, in both the home and intensive care units ("Noninvasive Ventilation: Overview, Methods of Delivery, General Considerations", 2020).

Furthermore, in NIV, positive airway pressure (PAP) modes of respiratory support are employed, which are commonly used for patients suffering from respiratory failure. This mode of ventilation is often used for patients with acute type 1 or 2 respiratory failure ("Positive airway pressure", 2020). Common types of PAP mechanisms of action include Continuous Positive Airway Pressure (CPAP) and Expiratory Positive Airway Pressure (EPAP). CPAP is a type of positive airway pressure, where air flow is introduced into the patient’s airways to maintain a continuous pressure for constantly keeping the airways open, in people who are breathing spontaneously (Gupta & Donn, 2016). CPAP is an effective way of maintaining Positive End-Expiratory Pressure (PEEP), which is the pressure in the alveoli above atmospheric pressure at the end of expiration.

The application of CPAP by maintaining PEEP and increasing the surface area of the alveolus, improves ventilation-perfusion (V/Q) matching, and hence, improves oxygenation (Gupta & Donn, 2016). EPAP is a type of positive airway pressure set during expiration, the lowest pressure during the respiratory cycle and is primarily used to splint additional alveolar units and smaller airways that may otherwise close during expiration in respiratory infection (Nicholson, Talbot, Nickol, Chadwick & Lawton, 2020). It is thus delivered by the ventilator while the patient is exhaling, maintaining the openness of the patient's airways until the next inhale (Margutti, Greco, Brambilla, Maraffi & Cosentini, 2017). This reduces deoxygenated blood flowing through areas of poorly ventilated lungs and effectively increases the surface area available for gas exchange, therefore improve oxygenation (Nicholson, Talbot, Nickol, Chadwick & Lawton, 2020).

This paper proposes the design of a small-wood unit to provide expiratory positive airway pressure (EPAP) for patients experiencing acute pulmonary distress due to COVID-19. The envisioned EPAP unit comprises a 2-liter graduated tight-lid water holding container with an expiratory port, a cork that is tightly fitted to the aerosol holder, which holds the immersed aerosol tube in water. The aerosol tube is then connected to the face mask through NIF-Tee. Oxygen is delivered through oxygen line attached to a port on the NIF Tee. (See **Error! Reference source not found.**). The rest of the paper is structured as follows: section two presents the literature review, section three explains the methodology, section 4 deals with the findings and section 5 presents the conclusion.

2. **LITERATURE REVIEW**

Ventilators have been in used for centuries. In many climates, architectural constructions took into consideration the dynamics of air flow to ensure that homes were adequately ventilator. The current usage of the ventilator, which are assistive mechanical devices started about the turn of the last century. Most of the existing advanced ventilator systems have two modes of ventilation, namely (i) Continuous -this is non-spontaneous breathing that is often used in case of sedation or when patients are comatose; (ii) Intermittent -this allows for spontaneous breathing where the patient can breathe between breaths. Modern Ventilator machines allow the following parameters and variables of respiratory function to be controlled to effectively deliver care to patients. (i) Pressure—the pressure of the airways (peak and plateau pressures); (ii) Tidal Volume 200-1000ml of spurts of air inhale by the patient during a breathing cycle; (iii) Rate of Respiration—10-18 breaths per min; (iv) Flow Rate - using ultrasonic, variable orifice (v) Amount of Oxygen—measured by the FiO_2. Additionally, the modes of controlling for patient breathing can be configured in any of the following modes: (i) Assist Control; (ii) Pressure Control; (iii) Pressure Support; (iv) CPAP/PEEP; (v) Synchronization of intermittent mandatory ventilation.

The challenges associated with these sophisticated ventilators include high cost, difficulties in maintenance, requirement for specialized operational training, access to electricity to run them and limited footprints in the developing world. As covid-19 is rapidly spreading across the world many places lack not just access to ventilators. In places where ventilators are available, they cannot be operated in the absence of electricity. These inherent challenges their consequences informed the design, development, and deployment of the Smallwood EPAP system. It is made from readily available components and does not require external energy sources for its operation. It depends on a reconfigured patient breathing circuits, and a container with sterile water. Current ventilator design includes the traditional off-shelf patient interface, which is essentially a pneumatic circuit that interfaces to the physical ventilator unit. The main ventilator unit has ports to connect the patient interface and internal electronic circuits for monitoring, regulating, and displaying controllable breathing parameters such as respiratory rate, flow rate, peak and plateau pressures. Sophisticated software systems ensure the tracking of each patient information such as name, age, weight, height and other demographical data to determine flow rate and other parameters as required by the clinician in the continuum of care.

3. DESIGN AND COMPONENTS

3.1 Design of Smallwood Respiratory System

The detail components of the SMALLWOOD device is shown in Figure 1. It comprises a NIT-Tee adaptor, an aerosol tube and tube holder, water holding graduated container, oxygen tube, face mask. The holding container is filled with sterile water to and has an inlet for the aerosol tube as well as expiratory port to allow expired air out of the container. The details components are expounded upon in the preceding sections.

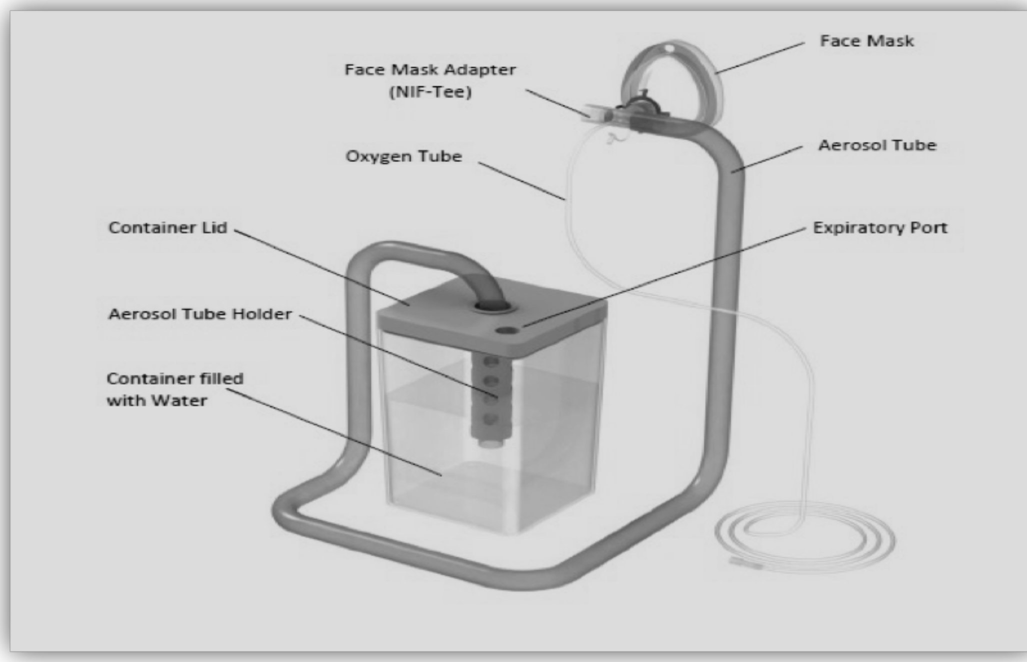

Figure 1. Detailed Design of The Small-Wood Respiratory System

3.2 NIF-Tee Adapter (Face Mask Adapter)

The NIF-Tee Adapter shown in Figure 2 provides interconnection for the oxygen unit, the Air, and the patient mask**.** When the patient inhales or breath in the air from the environment passes through the **inhalation port**. The inhalation, from the patient, exercises some back pressure on the valve, thus open the **one-way valve**. This allows the air to flow to the patient's lung. This air enters the lungs and the oxygen from the air moves from the lungs to the blood. At the exhalation or breath out, the patient exercises a forward pressure which closes back the one-way valve blocking the CO2 and waste gas to escape into the air. The pressure produced in the NIF-Tee Adapter will therefore move to the exhalation port. The CO2 and waste gas move to the exhalation port because of its big cross-sectional area. Sometimes the oxygen present in the air is not of high quantities, therefore an oxygen port is provided to connect the oxygen cylinder to the patient. The oxygen port has a small cross-sectional area.

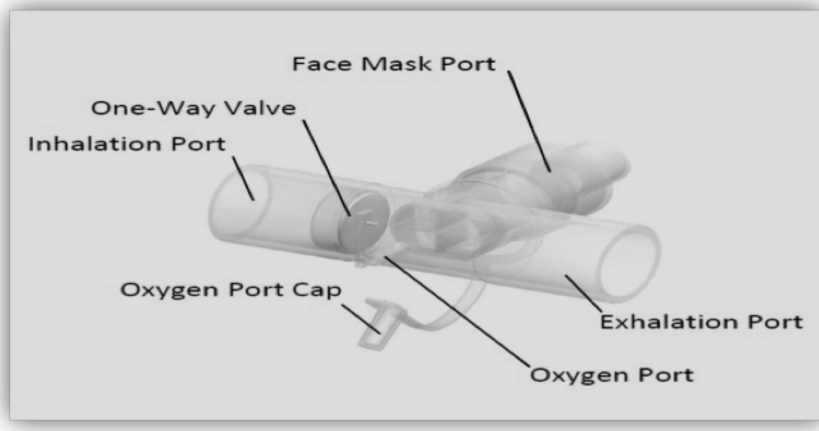

Figure 2: NIF-Tee Adapter (Face Mask Adapter)

1.1 Aerosol Tube and tube holder

The Aerosol tube shown in Figure 3 is a transmission medium to the container. The CO_2 and the waste gas pass through the aerosol tube and go into the container water. The tube is held stable by the aerosol tube holder. The holes present in the tube holder are used to create expiratory positive airway **pressure (EPAP)** delivered to the patient during exhalation. The hole on the container Lid is used as the expiratory port. To adjust the amount of the EPAP delivered by the device, adjust the depth of the aerosol.

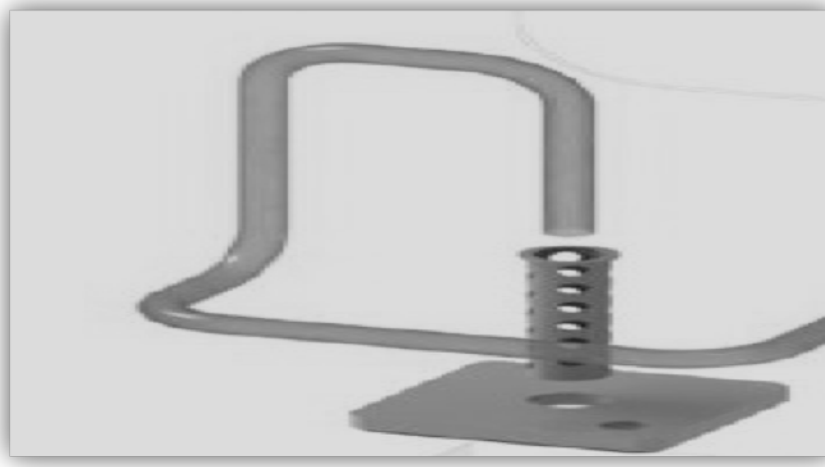

Figure 3. Aerosol Tube and Tube Holder

3.3 Container

The container is used to carry the water, the water together with the aerosol tube holder creates the expiratory positive airway **pressure (EPAP).**

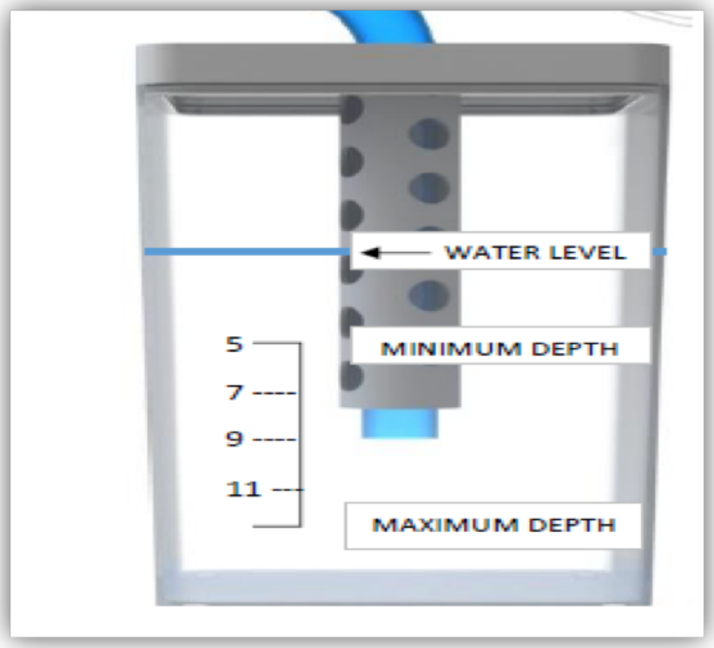

Figure 4: Container to Hold The Water

3.4 Face mask

The off-shell face mask is shown in
Figure 5
Figure 5 The face mask connects the patient to the **NIF-Tee Adapter.** It is directly connected to the patient nose whereby inhalation and exhalation happen.

Figure 5: Face Mask

3.5 Oxygen Tube

Figure 6: Oxygen Tube

Figure 6, shows the oxygen tube. This tube is a transmission medium to the oxygen cylinder. When the patient inhales, the oxygen in the cylinder passes through that tube to the patient's face mask and enters the into the lungs. Figure 7 shows a complete device assembly with face mask connection to the patient.

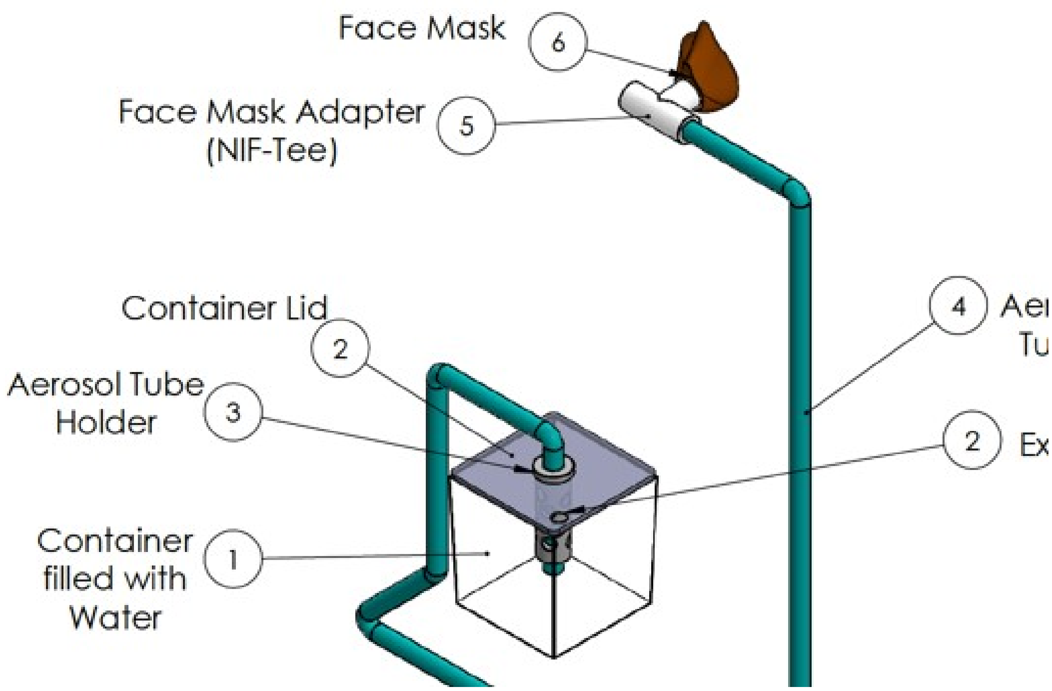

Figure 7: Complete Smallwood Device Assembly

The Smallwood **A**dult **P**ositive **Ex**piratory support device (APEX) works as a simple non-invasive Continuous Positive Airway Pressure (CPAP) without the need for electricity. The system is made up of an anaesthesia mask affixed to a

one-way T-piece valve, which is connected to a tube that is submerged in sterile water to generate end expiratory positive airway pressure (EPAP).
The depth to which the tubing is immersed underwater determines the magnitude of the continuous positive pressure applied to the airways. It was modelled along the principle, whereby via the face mask, room air or humidified oxygen is delivered to the patient and expired gases are completely expelled through unidirectional valves.

This is essentially an adult version of infant bubble CPAP with some modifications to enable use of low flow oxygen and ensure adequate EPAP levels at high inspiratory flow rates through the inclusion of a simplified manifold/diffusing system. Exhaled gases are then passed through a baffle system to capture aerosolized particles before exiting to the room.

The device is intended to provide CPAP for adults in respiratory distress in the absence of a mechanical ventilator or purpose-built CPAP machines. Figure 1 shows the design of Smallwood Respiratory System.

4. RESULTS

The compact, readily portable and inexpensive Smallwood EPAP system has been piloted with the faculty of Medicine at the University of Ghana. Preliminary finding indicates the system can reduce acute pulmonary distress.

5. CONCLUSION

The need to response to the ravaging effect of the Covid-19 pandemic and its possible devastation for low-income economies was the motivation behind the design, development, and deployment of the Smallwood EPAP system. The simple design and readily availability of accessories make for ease of design and adaption of the product for resource-limited environments. The added-advantage of this design is the ability to mass produce with minimum labor costs and point-of-care assembly. The Smallwood EPAP device in its simplicity lies tremendous opportunities to ameliorate the tragedy of Covid-19.

6. FUTURE WORKS

Our future work will provide illustrations of device being tested on patient. We will also measure parameters such as respiratory rate, flow rate, peak and plateau pressures for several time while selecting patient randomly to indicate device operation. We will also plot intelligent graphs with Matlab based on the data, perform statistical analysis to extract means, standard deviation and conclude with typical parameters for our design which can now be compared with other existing ventilator.

End Note

Dr. Craig Smallwood a graduate of the biomedical Engineering Program at Northeastern University and Respiratory Expert at Boston Children Hospital as well as an Assistant Professor at Harvard Medical School passed away on April 10th, 2020.

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